K03 1291

MAY - 5 2003

Exhibit IV: 510(k) Summary

Schick CDR PANX MODEL 4792

Common/Classification Name: "DIGITAL X-RAY EXTRAORAL SOURCE SYSTEM"
21CFR872.1800

Schick Technologies, Inc.
30-00 47th Avenue
Long Island City, NY 11101
718-937-5765, 718-937-5962 (FAX)
Contact: Daniel Michaeli, Prepared: April 10, 2003

A. Legally Marketed Predicate Devices

The Soredex Cranex Tome system is a legally marketed predicate device that emits x-ray radiation for panoramic radiographs. By default, the Soredex system utilizes x-ray film, however a digital receptor that subsequently received clearance under K982661, may also be used with the device. Schick Technologies has now demonstrated equivalence of a new integrated digital panoramic machine to the Soredex system.

B. Device Description

The CDR PanX Model 4792 is a digital panoramic device. A high voltage power supply charges an x-ray tube that emits a pulse which is attenuated by the patient's head. An FDA approved digital receptor receives the resultant image and transmits the data to a computer. The receptor and x-ray source both revolve on a motion stage such that multiple projections may be generated thereby resulting in a panoramic view of the skull. The computer processes and displays the image data on a monitor.

C. Indications for Use

The CDR PanX Model 4792 is indicated for individuals requiring extra-oral dental exams. It exposes and acquires radiographic images at the dento-maxillofacial region.

D. Substantial Equivalence Summary

The CDR PanX Model 4792 is substantially equivalent to digital panoramic units currently marketed in the U.S. The Soredex Cranex Tome is similar in that it is

indicated for, among other things, panoramic x-ray examinations of the maxillofacial region, although it traditionally utilizes film. It can, however, be retrofit with the CDR – PAN MODEL 4700, which is the same sensor as is utilized in this new integrated product.

E. Testing

A radiation survey has confirmed that the device exposes the patient to similar radiation as the predicate. In addition, the device conforms with electrical safety standards and 21CFR 1020.30-31.

F. Conclusions

Schick Technologies has demonstrated through careful analysis and validation studies that the device is substantially equivalent to the already cleared and marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2003

Schick Technologies
% Mr. Donald J. Sherratt
Medical Stream Director
Intertek Testing Services
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K031291
Trade/Device Name: CDR PanX
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 76 MUH
Dated: April 22, 2003
Received: April 23, 2003

Dear Mr. Sherratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031291

Device Name: CDR PanX

Indications For Use:

The CDR PanX Model 4792 is indicated for individuals requiring extra-oral dental exams. It exposes and acquires radiographic images at the dento-maxillofacial region.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

(Division Sign-Off)

of Reproductive, Abdominal,

Devices

Number K031291